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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,809	10/21/2003	Michael John Allen	014928/0000001	9427

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EXAMINER	
BOWERS, NATHAN ANDREW	
ART UNIT	**PAPER NUMBER**
1744	

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/690,809	ALLEN ET AL.	
	Examiner	Art Unit	
	Nathan A. Bowers	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *041405, 030105*. 052604
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 2 July 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

The Hagleitner "Smart Single-Chip Gas Sensor Microsystem" publication was not considered because it was not made readily available.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 6, 26 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The relationship between the terms "sample" and "specimen" as used in claims 1, 2, 5 and 6 is unclear. It is examiner's understanding that the terms "medium" and "sample" are used to refer to aqueous solutions, and that the term "specimen" refers to a specific analyte found in the medium and sample. See paragraphs [0002] and [0037] of the specification. However, it is unclear as to how the "samples" can be biological cells (as in claims 5 and 6), while including at least one specimen (as in claim 2).

Claim 26 recites the limitation "the specimens" in line 4 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 27 recites the limitations "said assembly" and "said cantilever" in lines 5 and 6 of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claims 1-5, 8, 13-18 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Furcht (US 6054277).

With respect to claims 1-5 and 8, Furcht discloses a motion sensor comprising a chamber (Figure 2:65) for holding a medium that includes a biological sample comprising DNA specimens. At least one force transducing sensor (Figure 8:71) is positioned to interact dynamically with the sample. Column 4, lines 15-57 and column 5, line 31 to column 6, line 17 indicate that the force transducing sensor is a MEMS microcantilever device that is capable of binding to specific biological specimens. The subsequent deflection of the microcantilever (or change in vibration frequency) caused

by the adherence of an analyte is electrically detected by a system of electrodes (Figure 7:74 and Figure 7:75). This is disclosed in column 10, line 54 to column 11, line 9.

With respect to claims 13-18, Furcht discloses the apparatus as discussed above, wherein the force transducing sensor comprises a biologically active surface coating designed to bind specifically with specimens in the sample fluid. Column 11, lines 10-17 teach that actuating polymers (Figure 8:90) are deposited upon the microcantilever. Figure 7 and column 10, line 63 to column 11, line 9 indicate that multiple microcantilevers are provided in the form of reference sensors and detection sensors.

2) Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by Thundat (US 6289717).

Thundat discloses a method for determining characteristics of a sample under analysis comprising the steps of providing at least one force transducing sensor (Figure 1:3) having a surface. This is disclosed in column 2, lines 21-36 and in column 3, lines 31-49. Column 4, lines 15-41 indicate that the surface has a coating thereon capable of interacting with biological specimens in the sample fluid. Resulting interactions between the specimens and the coated surface of the force transducing sensor are identified. Column 5, lines 1-15 teach that by detecting the motion of the force transducing sensor, one is able to determine the presence of cellular analytes in the sample fluid.

3) Claims 1-5, 7, 8, 13-18 and 21-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Welland (US 20030222232).

With respect to claims 1-5, 7 and 8, Welland discloses a motion sensor comprising a chamber (Figure 1:4) capable of holding a medium wherein the medium includes a sample. Paragraphs [0001] and [0002] indicate that the motion sensor is designed to determine the presence of pharmaceutical analytes in a biological sample fluid. According to paragraphs [0005]-[0009], the chamber includes at least one force transducing sensor (Figure 1:3) in the form of a microcantilever positioned to interact dynamically with the sample. Paragraph [0031] teaches that a photodiode (Figure 1:2) is provided for detecting light reflected off of the microcantilever from a laser diode (Figure 1:1). This allows one to determine when and to what degree the force transducing sensor interacts with analytes in the biological sample.

With respect to claims 13-18, Welland discloses a motion sensor system comprising a chamber (Figure 1:4) adopted to receive a medium having therein a multiplicity of specimens. At least one force transducing sensor (Figure 1:3) in the form of a microcantilever is positioned within the chamber so as to be immersed in the medium during operation. A motion detector (Figure 1:2) is capable of determining binding of the microcantilever to biological specimens. Additionally, the surfaces of the force transducing sensor may be modified with coatings in order to facilitate effective binding to a desired analyte. This is disclosed in paragraphs [0005]-[0009] and [0031]. Paragraphs [0007] and [0036] and Figure 2 indicates that the motion sensor may include at least two cantilevers.

With respect to claims 20-25, Welland discloses a motion sensor system comprising a chamber (Figure 1:4) adopted to receive a medium having therein a multiplicity of specimens. At least one force transducing sensor (Figure 1:3) in the form of a microcantilever is positioned within the chamber so as to be immersed in the medium during operation. A motion detector (Figure 1:2) is capable of determining binding of the microcantilever to biological specimens. Although not expressly stated, Welland's device is inherently capable of detecting motile cells, such as sperm, since microcantilever detection devices are provided with coatings that encourage the adherence of desired biological analytes. In claims 21-25, Applicant does not cite any critical structural elements designed to accommodate motile cells that are not anticipated by Welland.

With respect to claim 26, Welland discloses a method for determining characteristics of a sample under analysis comprising the steps of providing at least one force transducing sensor (Figure 1:3) having a coated surface capable of interacting with biological specimens in the sample fluid. This is disclosed in paragraphs [0005]-[0009]. Resulting interactions between the specimens and the coated surface of the force transducing sensor are identified. Paragraph [0031] teaches that by detecting the motion of the force transducing sensor, one is able to determine the presence of biological analytes in the sample fluid.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4) Claims 1-8 and 12-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thundat (US 6289717) in view of Thundat (US 6016686).

With respect to claims 1-8, Thundat '9717 discloses a motion sensor comprising at least one force transducing sensor (Figure 1:3) is provided in the form of a microcantilever that is positioned to interact dynamically with a specimen (Figure 1:13) in a fluid sample. Column 2, lines 22-36 and column 3, lines 31-49 indicate that a variety of biological specimens, such as cells, are capable of binding to a microcantilever. Changes in the subsequent deflection of the microcantilever can be detected in order to determine the presence and motion of the specimens. Column 5, lines 1-15 teach that this motion of the force transducing sensor can be measured by deflecting light from a laser (Figure 1:17) off of the microcantilever and onto a photodetector (Figure 1:19). Thundat '9717, however, does not expressly disclose a chamber capable of holding the motion sensor and the biological medium to be analyzed.

Thundat '6686 discloses a similar motion sensor device. Column 3, line 51 to column 4, line 29 indicates that a microcantilever (Figure 1:3) is capable of detecting and measuring changes in the presence of certain physical and chemical parameters within the sample solution, such as hydrogen ion concentration. Since changes in the hydrogen ion concentration of biological samples is often linked to the activity of living organisms, deflections in the microcantilever can also be used to determine the

presence of cells. This is taught in column 10, lines 10-17. A chamber (Figure 10) for containing the motion sensor and biological fluids is disclosed.

Thundat '9717 and Thundat '6686 are analogous art because they are from the same field of endeavor regarding motion sensors comprising microcantilever devices.

At the time of the invention, it would have been obvious to provide the apparatus disclosed by Thundat '9717 with a chamber capable of holding the biological medium and the force transducing sensor. The use of a chamber would have been advantageous because it would have allowed one the ability of conducting experiments in a clearly defined and contained structure that is protected against external contamination. Furthermore, a holding chamber for enclosing a sample would have been an essential and intrinsic component of any detection system involving the analysis of liquids. The use of chambers in biological analytical procedures to contain fluids and instruments is well known in the art.

With respect to claim 12, Thundat '9717 and '6686 disclose the apparatus set forth in the 35 U.S.C. 103 rejection above. In addition, Thundat '9717 discloses in column 3, lines 62-64 that the width of the microcantilever force transducing sensor may be manipulated in any way to produce a variety of desired shapes. It would have been beneficial to ensure that the tip of the microcantilever had a longer width than the base in order to create a large analyte binding area at the end. A thinner base region would have provided the microcantilever with more flexibility when deflected by biological specimens, which in turn would create a more sensitive detector.

With respect to claims 13-19, Thundat '9717 and '6686 disclose the apparatus set forth in the 35 U.S.C. 103 rejection above. In addition, Thundat '9717 discloses in column 4, lines 15-40 that the surface of the force transducing sensor may be coated with a biologically active material in order to facilitate binding with appropriate specimens in the medium. Column 6, lines 39-45 teach that an untreated reference microcantilever (Figure 2:15) may be provided in close proximity to the detection microcantilever (Figure 2:3).

With respect to claims 20-25, Thundat '9717 and '6686 disclose the apparatus set forth in the 35 U.S.C. 103 rejection above. Although not expressly stated, the device proposed by Thundat '9717 is inherently capable of detecting motile cells, such as sperm, since microcantilever detection devices are provided with coatings that encourage the adherence of desired biological analytes. In claims 21-25, Applicant does not cite any critical structural elements designed to accommodate motile cells that are not anticipated by Thundat '9717.

5) Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Welland (US 20030222232) as applied to claim 1, and further in view of Negersmith (US 4300906).

Welland discloses the motion sensor set forth in claim 1 as set forth in the 35 U.S.C. 102 rejection above, however does not expressly disclose that the medium is pumped either at a constant rate or with repetitive pulses.

Negersmith discloses a method and apparatus for pumping biological samples from a source (Figure 1:18 and Figure 1:12) to an analysis unit (Figure 1:34). This is taught in column 1, line 34 to column 2, line 2. Column 3, line 59 to column 4, line 65 indicate that pumps are provided that are capable of providing constant and pulsatile flow rates to the analytical device.

Welland and Negersmith are analogous art because they are from the same field of endeavor regarding laboratory experimentation systems.

At the time of the invention, it would have been obvious to incorporate into Welland's analytical device a fluid delivery mechanism capable of providing constant and pulsatile flow rates. Negersmith teaches in column 1, line 34 to column 2, line 2 that the ability to accurately deliver a desired quantity of fluid is often essential in order for many analytical devices to provide exact results. It would have been advantageous to move biological samples to Welland's motion sensor constantly or in pulses, since it would have allowed one to determine how much fluid was being added to the motion sensor over a period of time. This in turn would have allowed one to more clearly interpret the results obtained by the sensor.

6) Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Furcht (US 6054277) as applied to claim 1, and further in view of Polla (US 5536963).

Furcht discloses the motion sensor set forth in claim 1 as set forth in the 35 U.S.C. 102 rejection above, however does not expressly disclose that the force transducing sensor includes a ribbon.

Polla discloses a plurality of microcantilevers that may deform when acted upon by a force. The degree of deformation may be determined optically. This is disclosed in Figure 1 and in column 3, line 57 to column 4, line 32. Figure 3 and column 5, lines 36-63 disclose one embodiment in which the microcantilever (Figure 3:14) is supported by a substrate on both ends to form a ribbon structure.

Furcht and Polla are analogous art because they are from the same field of endeavor regarding microcantilever sensors.

At the time of the invention, it would have been obvious to form Furcht's force transducing sensor in such a way that the microcantilever structure was supported on both ends to form a ribbon. This would have been beneficial because it would have allowed one to produce a sturdier micromachined sensor that would have been less susceptible to breakage when contacted by analytes in solution. In doing this, the functionality of Furcht's apparatus would not have been lost, since deflections at the center of the ribbon cantilever sensor would still have been able to be detected by the disclosed optical system.

7) Claims 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Welland (US 20030222232) in view of Paritsky (US 20030209656).

Welland discloses a nanomotion sensing system comprising a laser light source (Figure 1:1) and a photodetector (Figure 1:2) that are optically aligned with a MEMS force transducing sensor (Figure 1:3). The force transducing sensor is in the form of a cantilever, and the motion of the cantilever is detected by the photodetector. Welland,

however, does not disclose a transparent substrate that is attached to the force transducing sensor on a first surface, and is affixed to the light source and photodetector on a second surface. Welland does not disclose a transparent substrate that includes at least one lens.

Paritsky discloses an optical sensor that is capable of determining very small deformations in a membrane (Figure 1:5). The membrane is attached to a second surface of a transparent substrate (Figure 1:6), and a first surface of the substrate is affixed to a light source (Figure 1:3) and a photodetector (Figure 1:4) through a base plate (Figure 1:2). In this way, the substrate, light source, photodetector and sensor are integrated into a single optical assembly. This is disclosed in paragraphs [0005], [0006] and [0021]-[0024]. The transparent substrate includes lenses (Figure 1:13 and Figure 1:10) that direct light to the membrane from the light source and to the photodetector from the membrane.

Welland and Paritsky are analogous art because they are from the same field of endeavor regarding optical detection mechanisms.

At the time of the invention, it would have been obvious to incorporate a transparent substrate into the nanomotion sensing system disclosed by Welland in order to integrate the light source, photodetector, and cantilever into a single optical assembly. The use of the transparent substrate is advantageous because it may be used as a waveguide to direct light and record measurements, and also as a support which is capable of integrating all of the components of the sensing system into one unit. Paritsky teaches in paragraphs [0003]-[0005] that optical sensors arranged in this

fashion are capable of obtaining very accurate measurements of very small cantilever deformations. Independent sensing units that comprise a transparent membrane in combination with a force transducing sensor, light source, and photodetector readily lend themselves to mass production at relatively low costs.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 4, 7, 13, 16, 17 and 26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 12-15 and 22 of U.S. Patent No. 6642517 in view of Thundat (US 6016686).

U.S. Patent No. 6642517 discloses a motion sensor comprising a force transducing sensor in the form of a cantilever. A light source and á photodetector are

provided for determining changes in the position of the cantilever. U.S. Patent No. 6642517, however, does not disclose a chamber containing a sample that is capable of interacting dynamically with the cantilever.

Thundat '6686 discloses a motion sensor device that includes a microcantilever (Figure 1:3) which is capable of detecting and measuring changes in the presence of certain physical and chemical parameters within the sample solution, such as hydrogen ion concentration. This is disclosed in column 3, line 51 to column 4, line 29. Since changes in the hydrogen ion concentration of biological samples is often linked to the activity of living organisms, deflections in the microcantilever can also be used to determine the presence of cells. This is taught in column 10, lines 10-17. A chamber (Figure 10) for containing the motion sensor and biological fluids is disclosed.

It would have been obvious to provide the apparatus disclosed by the referenced patent with a chamber capable of holding the biological medium and the force transducing sensor. The use of a chamber would have been advantageous because it would have allowed one the ability of conducting experiments in a clearly defined and contained structure that is protected against external contamination. Furthermore, a holding chamber for enclosing a sample would have been an essential and intrinsic component of any detection system involving the analysis of liquids. The use of chambers in biological analytical procedures to contain fluids and instruments is well known in the art.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Bashir (US 6935165), Gimzewski (US 20050239047) and Prater (US 20020092340) references disclose the state of the art regarding force transducing sensors.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on (571) 272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NAB

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